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Hand Biomechanics Lab

510(k) Summary

Owner Information: Hand Biomechanics Lab, Inc.
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Date Prepared: December 31, 2007

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Name of Device: Trade Name: F3 Fractured Finger Fixator
Common Name: External Fixator System
Classification Name: Component, Traction, Invasive [21CFR 888.3040, Product Code JEC]

Predicate Device: Compass PIP Joint Hinge (Smith & Nephew, Inc. Orthopedic Div.), K970713

Description of Device:

The F3 Fractured Finger Fixator is an external skeletal fixator designed to obtain and maintain concentric reduction of an unstable dorsal fracture-dislocation of the proximal interphalangeal (PIP) joint. This device exerts a volarly translating force on the middle phalanx while simultaneously lifting the distal end of the proximal phalanx to restore joint alignment. With the dorsal dislocation of the middle phalanx reduced, the fractured fragments of the joint surface are reopposed. The effect of the F3 is present throughout the complete range of finger motion allowing full active flexion and extension during healing of the bone and soft tissues.

Included with the F3 is a custom designed Pin Placement Guide that allows for a Transverse Bone Pin to be accurately placed through the axis of PIP joint rotation. The Dorsal Bone Pin is inserted vertically into the middle phalanx. The F3 device is installed on the Dorsal Bone Pin and is linked to the Transverse Bone Pin with Elastic Bands. These bands provide the translating force that holds the joint concentrically reduced. A Tension Adjust Screw on the F3 allows the surgeon to "fine tune" the amount of tension in the Elastic Bands so they exert the least amount of tension necessary to maintain joint alignment.

The F3 Fractured Finger Fixator is manufactured using metal and plastic. The bone pins are fabricated from 316L stainless steel per ASTM F138. Both latex and non-latex elastic bands are supplied with the device. All components are designed for single use only.

Intended Use:

The F3 Fractured Finger Fixator is indicated for the treatment of acute, unstable dorsal fracture-dislocations of the proximal interphalangeal (PIP) joint of the fingers in which external skeletal fixation as provided by the F3 Fractured Finger Fixator alone is sufficient to obtain and maintain concentric reduction of the fracture-dislocation during bone and soft tissue healing.

Technological Characteristics Compared to Predicate Device:

The F3 is comparable to the predicate device with respect to function and application technique. Both are indicated for unstable dorsal fracture-dislocations of the PIP joint and are attached to the finger using bone pins. The F3 uses elastic bands to apply reduction forces across the PIP joint, whereas the predicate device uses a distraction screw to apply traction and an engageable worm gear to control flexion-extension of the PIP joint. The F3 and predicate device are both made of plastic and metal components. The F3 is delivered to the customer in either sterile or non-sterile form. In the non-sterile model, the customer is responsible for sterilization before use. The predicate device is supplied sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Hand Biomechanics Lab., Inc.
% Mr. Jeff Woodhouse
77 Scripps Drive
Suite 104
Sacramento, CA 95825-6209

Re: K072432
Trade/Device Name: F3 Fractured Finger Fixator
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JEC
Dated: January 2, 2008
Received: January 3, 2008

Dear Mr. Woodhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K072432

Device Name: **F3** Fractured Finger Fixator

Indications for Use:

The F3 Fractured Finger Fixator is indicated for the treatment of acute, unstable dorsal fracture-dislocations of the proximal interphalangeal (PIP) joint of the fingers in which external skeletal fixation as provided by the F3 Fractured Finger Fixator alone is sufficient to obtain and maintain concentric reduction of the fracture-dislocation during bone and soft tissue healing.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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